



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,364	12/05/2003	Raymond W. Sze	UNIV0162	8253

7590 03/18/2008  
Michael C. King  
LAW OFFICES OF RONALD M. ANDERSON  
Suite 507  
600-108th Avenue N.E.  
Bellevue, WA 98004

EXAMINER
----------

UTAMA, ROBERT J

ART UNIT	PAPER NUMBER
----------	--------------

3714

MAIL DATE	DELIVERY MODE
-----------	---------------

03/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,364	<b>Applicant(s)</b> SZE ET AL.	
	<b>Examiner</b> ROBERT J. UTAMA	<b>Art Unit</b> 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-27 and 52-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-27 and 52-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3714

## **DETAILED ACTION**

### ***Status of the Application***

1. This office action is a response to the amendment and argument and filed on: 01/22/2008. The current status of the application are as follow: claim 1-2, 4-27 and 52-58 are still pending. Claims 3 and 28-51 have been cancelled.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/22/2008 has been entered.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**4. Claim 1-2, 4—27 and 52-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Gain et al US 4,708,836, in view of NPL#1 and further in view of Cecchi 2003/0208101.**

**Claim 1 and 21:** Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of “the echogenicity of the second

Art Unit: 3714

material being substantially different than an echogenicity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model.” The difference in density of the first material –epoxy resin- and the second material – oil and silicon mixture- would have resulted in a difference in echogenicity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

**Claim 2:** Gain provides a teaching for a medical simulator having a second material that fills opening in the first material (see col. 12:44-56). However, Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as

Art Unit: 3714

taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

**Claim 4 and 23:** While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

**Claim 5 and 22:** While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

**Claim 6:** Gain provides a teaching where the model includes a scalp portion which include a scalp portion (see Gain FIG 15) and the scalp portion of the model is covered in layer of the second material, the second material covering at least a portion of the first material (see Gain col. 12:44-56). The limitation of “to prevent the simulated patent sutures from being identified tactilely” is being treated as an intended use limitation and currently not given patentable weight.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically

Art Unit: 3714

correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

**Claim 7-9:** The examiner contends that the reference of Gain and NPL #1 fails to show an ultrasound simulator with a patent suture that is filled with a mixture of starch and glue (**claim 7**). Similarly, the reference does not show the glue in the mixture to be a casein-based glue (**claim 8**) or a synthetic resin-based glue (**claim 9**). Instead, the combination of the Gain and NPL#1 reference used a mixture of oil and silicon (see col. col. 11:45-57).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model the sutures using a mixture of oil and silicon.or starch and glue mixtures. Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, the echogenicity of both materials are less than then solid portion of the skull. Therefore, it would have been prima facie obvious to modify Gain and NPL #1 to obtain the invention as specified in claim 7-9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Gain and NPL#1.

**Claim 10 and 11:** Gain fails to provide a teaching of having a simulated patent skull sutures. The infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagittal and lambdoid sutures. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

Art Unit: 3714

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasound device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

**Claim 12:** Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures (see Gain FIG. 2).

**Claim 13:** Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures made from a first material (see Gain col. 5:43-67 artificial cranium).

**Claim 14 and 25:** The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening form in said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

However, the examiner views the current claim as a product by process limitation.

*“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (see MPEP 2113). In this particular case the Gain reference provides a*

Art Unit: 3714

teaching of a simulated fused skull suture (see FIG 2 between item 2 and 6). The Gain reference does not provide a teaching of having a simulated fused skull suture being filled a third material. Instead the Gain reference shows that a patent suture filled with the first material. While Gain et al is silent on the limitation of “the echogenicity of the second material being substantially different than an echogenicity of said first/third material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model.” The difference in density of the first material –epoxy resin- and the second material – oil and silicon mixture- would have resulted in a difference in echogenicity such that the first/third and second material is readily distinguished in an ultrasound image of said model.

**Claim 15 and 55:** The Gain reference fails to provide a teaching wherein the echogenicity of the third material is substantially similar to the first material, such that in an ultrasound image of the model, portions of the model comprising the first material are not readily distinguishable from portions of the model comprising the third material.

However, the Gain reference provides a teaching of having a patent suture filled with the first material (see FIG 2 between item 2 and 6). However, the same result can also be achieved by using the first material for the third material. Since they are made from the same material, the material should have similar echogenic properties.

**Claim 16-17 and 56:** The Gain reference fail to provide the third material comprises a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers and silica.

Instead the Gain reference provides a teaching of using epoxy resin instead of a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers and silica as claimed.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use epoxy-resin, because Applicant has not disclosed that a synthetic elastomer and the elastomer comprises of dimethyl siloxane,



Art Unit: 3714

hydroxyl-terminated polymers, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the epoxy resin and a synthetic elastomer, to perform equally well for the purpose of having the same echogenic properties as the first material.

Therefore, it would have been prima facie obvious to modify Gain to obtain the invention as specified in claim 16-17 and 56 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Gain.

**Claim 18 and 19:** Gain provides a teaching of an opaque layer configured to cover each of the simulated skull sutures and the scalp areas (see col. 12:44-56). The limitation of “so that a trainee cannot readily visually determine whether a specific skull sutures is patent or skull by inspecting the model” is being treated as an intended use limitation and currently not given patentable weight.

**Claim 20:** Gain provides in teaching where the head is utilized for the substantially life size model of a human head (see col. 2:7-14).

**Claim 26:** Gain fails to provide a teaching of having a simulated patent skull sutures. However, the infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagital and lambdoid sutures. The reference also shows that the sagital and metopic sutures are formed in a way that the opposites walls of the opening would meet in an end-to-end fashion. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a

Art Unit: 3714

person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasonic device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 26 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

**Claim 27:** Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of “the echogenicity of the second material being substantially different than an echogenicity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model.” The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenicity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant. While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil

Art Unit: 3714

and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark

**Claim 52:** Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain et al is silent on the limitation of “the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model.” The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

**Claim 53:** Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain et al is silent on the limitation of “the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model.” The examiner takes the position that the difference in density of the first material –epoxy resin- and the second

Art Unit: 3714

material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

**Claim 54 and 57:** Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of “the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model.” The difference in density of the first material –epoxy resin- and the second material – oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagittal, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it

Art Unit: 3714

would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening form in said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

However, the examiner views the current claim as a product by process limitation.

*“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (see MPEP 2113).* In this particular case the Gain reference provides a teaching of a simulated fused skull suture (see FIG 2 between item 2 and 6). The Gaim reference does not provide a teaching of having a simulated fused skull suture being filled a third material. Instead the Gain reference shows that a patent suture filled with the first material. While Gain et al is silent on the limitation of “the echogenicity of the second material being substantially different than an echogenecity of said first/third material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said

Art Unit: 3714

model.“ The difference in density of the first material –epoxy resin- and the second material – oil and silicon mixture- would have resulted in a difference in echogenecity such that the first/third and second material is readily distinguished in an ultrasound image of said model.

### ***Response to Arguments***

5. Applicant's arguments filed 01/22/2008 have been fully considered but they are not persuasive.

6. With respect to claim 1, 21, 27-29 and 45; the applicant set forth the argument of the that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture would not be readily distinguishable in an ultrasound image. The examiner respectfully disagrees. While, the applicant claim that applicant have empirical studies that proves otherwise, the applicant has not submitted such evidence. Hence, the examiner cannot determine the validity of the applicant's assertion. Accordingly, the examiner has pointed new citation that shows that one can adjust the echogenic properties of a material by using different material with different densities.

7. The applicant also present that arguments that the Gain reference does not provide explicit teaching of adding patent sutures and the lack of explicit teaching made the obviousness rejection invalid. The examiner respectfully disagrees. There is no requirement that the explicit teaching from the prior art is required when making an obviousness type of rejection. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law (see MPEP 2144). In this particular case, the examiner argues that adding the patent sutures (both fused and unfused) would have been beneficial since the model can correctly describe the mechanical properties of an infant. With respect to claim 27, the applicant argues that the Gain reference does not have

Art Unit: 3714

a teaching that a fused patent suture to be used in a crash purpose model. The examiner respectfully disagrees, since the applicant is arguing an intended use of the prior art. However, even if the examiner were to take applicant's argument, the examiner argues that having a fused skull suture would have presented a different mechanical properties from an adult human cranium or a healthy infant. Hence, one of ordinary skilled in the art would have been motivated to make the modification since it would allow the system to test different scenario, in this particular case a model of a baby having a craniosynostosis condition.

8. With respect to claim 14-17 and 25, new rationale of rejection has been applied to the claim limitation. The claim limitations are treated as a product by process claim. *“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (see MPEP 2113).* In this particular case, the examiner argues that the one of ordinary skilled in the art could have used the same material (as the first material) to make the third material. This material would still follow the limitation of claim 14, where *“the third material is substantially distinguishable from the second material”*. As such claim 54-58 have also been rejected under the same rationale.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT J. UTAMA whose telephone number is (571)272-1676. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezutto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3714

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. U./  
Examiner, Art Unit 3714

/Ronald Laneau/  
Supervisory Patent Examiner, Art Unit 3714  
03/13/08